

ANNUAL DUR REPORT

DRAFT

FFY 2004 (October 1, 2003 – September 30, 2004)

Washington State

ATTACHMENT 1: MONITORING OF ORAL COUNSELING COMPLIANCE

The State of Washington addresses the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) through its universities and the Washington State Board of Pharmacy. The act is presented to pharmacy students in the two Washington universities with colleges of pharmacy and monitored by the Board of Pharmacy in its investigation and inspection process in the field.

Pharmacists in Washington State are required to counsel all patients or the patient's agent or caregiver in all ambulatory care settings where patients receive prescriptions, and the content of the counseling must meet the OBRA 90 requirements. The counseling is preferably done in person, but may be done in writing as long as free access to a pharmacist is provided by phone. Some retail pharmacies document the counseling in daily signature logs.

The pharmacy students are taught prospective drug review measures (DUR) by screening prescriptions prior to dispensing the medications and counseling the patient with appropriate information for the drugs prescribed. The students are taught to detect potential drug errors and to use their learned skills to resolve potential medication problems. The pharmacy student learns to consider the prescribed drug therapy and then apply their clinical skills to the appropriateness of the therapy. This may entail direct communication with the prescriber or research to resolve a potential problem using their knowledge base. The idea here is to improve the quality of drug therapy and thereby ensure a positive outcome for the patient. The students are taught to offer (provide) counseling to the patient on the use of the medication that is particularly relevant to the patient's circumstances. This may include dosage, route of administration, duration of therapy, special directions and precautions. Other considerations may include adverse effects, medication interactions, therapeutic contraindications, proper storage, and refill information. However, it must be noted that pharmacists may withhold information when it is deemed in the best interest of the patient. Of course, the patient has the right to refuse this counseling and should so be documented by the pharmacist.

After learning these skills in the classroom, the students are expected to transfer them to the laboratory. These are conditions where much therapeutic situations are used to dramatize potential drug therapy problems. The pertinent issues are addressed, communication is made with the prescriber, the intervention or relative information is documented, and the patient is counseled. Both universities use this basic approach in teaching the future pharmacists in the State of Washington in the pharmaceutical care of their patients.

The State Board of Pharmacy inspects all pharmacies licensed in Washington State periodically. As part of these inspections, the State Board of Pharmacy observes counseling by the pharmacists in their practice settings and citations are given to pharmacies when the pharmacist fails to counsel patients during the inspection. The State Board of Pharmacy also receives complaints from patients reporting that a pharmacist has not counseled them appropriately. The Medical Assistance Administration (MAA) requires pharmacy providers to conform to all Washington State Board of Pharmacy rules.

During 2004, there were 386 complaints filed with the Board of Pharmacy. Ten (2.6%) of those complaints were related to drug counseling issues. During this same time period, there were 909 pharmacy inspections performed. There were 13 counseling related infractions found for a rate of 1.4%.

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ATTACHMENT 2: PROSPECTIVE DUR SUMMARY REPORT

Reports

2-1 Pharmacy Eligibles, Users and Claims by Month

2-2 Response to P.O.S. DUR Alerts: Summary Report

2-3 Response to P.O.S. DUR Alerts by Alert Type

2-4 Response to P.O.S. DUR Alerts by Therapeutic Category

Appendices

Appendix A List of MAA-Approved NCPDP DUR Codes

Appendix B List of Therapeutic Category Codes with Descriptions

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ATTACHMENT 3: RETROSPECTIVE DRUG USE REVIEW

Affiliated Computer Services (ACS) conducts retrospective Drug Use Review (DUR) under the direction of the Medical Assistance Administration (MAA) with the assistance of the Oregon Health and Science University, Evidence Based Practice Center (OSHU-EPC). The source of the DUR criteria is developed through the Drug Utilization Review (DUR) Board, who adopts criteria from other states/universities, revises other criteria developed outside the state such as established guidelines or standards of care, or creates the criteria within the Board. The Board does not adopt all the criteria presented to it.

RETRO DUR ACTIVITIES

1. Collaborative Asthma Education Project

At the November 13, 2002 Drug Utilization Education Council (DUEC) meeting, Dr. Yorioka reported the results of the collaborative asthma education subcommittee. The subcommittee recommendations adopted by the DUEC were as follow:

- Adopt the American Lung Association Asthma Action Plan for dissemination by drug representatives;
- Include a promotional statement regarding the use of office spirometry in the letter to drug manufacturers to be mailed out January 1, 2003.

2. Therapeutic Consultation Services: Intensified Benefits Management

- For October-December 2002, the HMG CoA inhibitors were targeted. Recommendations for the preferred agent were based on the desired LDL reduction and drug interaction potential. In October there was a 23% response rate with 16% of these accepting the IBM recommendations. The estimated annual savings for October is \$33,455. In November the response rate was 23% with 20% of those accepting the IBM recommendation. In December the response rate was 24% with 17% of these accepting the IBM recommendation.
- In January 2003 those patients receiving Angiotensin Receptor Blockers (ARB) as first line therapy without a trial of an Angiotensin Converting Enzyme Inhibitor (ACEI) were targeted. ARBs were considered for first-line therapy in patients with Type 2 diabetes and albuminuria/nephropathy or hypertension. There was a 52% response rate and 14% of these accepted the IBM recommendation.
- In February 2003 those patients receiving Calcium Channel Blockers as first line therapy for hypertension were targeted. There was a 33% response rate in which 11% accepted the IBM recommendation.

- In March and April 2003 those patients receiving non-sedating antihistamine were targeted, with promotion of the preferred drug, OTC loratadine.

3. NSAIDS and Cox-2 Inhibitors Class Review

The Pharmacy & Therapeutics (P&T) Committee/DUR Board reviewed the utilization of NSAIDs and Cox-2 inhibitors in February 2003. MAA has all NSAIDs on expedited prior authorization with criteria that requires the patient not have a history of GI ulcer or bleed. The Cox-2 inhibitors are also on expedited prior authorization, which limits the use of these agents to the FDA approved indications and dosing. The DUR Board recommended that the patient must have tried and failed or be found intolerant to at least two preferred NSAIDs and have no history of GI bleed before using a NSAID, including a Cox –2 inhibitor. Generic NSAIDs are preferred and will be kept on expedited prior authorization with the criteria that the patient must not have a history of GI ulcer or bleed.

4. Triptans Class Review

In February 2003 the P&T Committee reviewed the utilization of triptans. Dr. Helfand from OSHU Evidence Based Practice Center gave an overview of the triptans. The Committee recommended rizatriptan 10mg oral tablets be chosen as the preferred drug in the triptan class. In addition, sumatriptan 100mg oral tablets should be available for patients that also use the injectable or nasal forms of sumatriptan.

5. Dihydropyridine Calcium Channel Blockers Class Review

The P&T Committee reviewed calcium channel blocker utilization in February 2003. The Committee recommended nifedipine sustained release forms and amlodipine be chosen as preferred drugs.

6. Long-acting Opioid Class Review

The utilization of these agents during fiscal year 2002 was reviewed by the P&T Committee in March 2003. Daniel Baker, Pharm.D. from the Washington State University Drug Information Center reviewed the use of long acting opioids for chronic non-cancer pain. Dr. Chou from the OSHU-EPC presented the evidence based class review. The Committee recommended that methadone and long acting morphine be the preferred drugs in the long-acting opioid drug class for chronic non-cancer pain.

7. Skeletal Muscle Relaxant Class Review

The utilization of skeletal muscle relaxants was reviewed by the P&T Committee in March 2003. Dr. Baker and Dr. Chou provided an overview of the skeletal muscle relaxants for the council. The council recommended that cyclobenzaprine, chlorzoxazone, methocarbamol, baclofen, baclofen in combination with aspirin be chosen as the preferred drugs within the skeletal muscle relaxant class.

8. Treatment of Urinary Incontinence Drug Class Review

The utilization of drugs to treat urinary incontinence was reviewed by the DUEC in April 2003. Donna Marshall, Pharm.D. consultant pharmacist with UMP/HCA gave an overview of the drug class to the council. Marian McDonagh, Pharm.D. of the OSHU-EPC presented the evidence based review. The P&T Committee recommended that oxybutynin IR be chosen as the preferred anticholinergic drug for urinary incontinence. The Committee also recommended that flavoxate should not be approved for urinary urge incontinence because it was shown to be no better than placebo.

9. Oral Hypoglycemic Class Review

The utilization of oral hypoglycemic agents was reviewed by the P&T Committee in May 2003. Daniel Baker Pharm.D. provided an overview of the treatment and progression of diabetes. Mark Helfand, MD presented the evidence-based report on oral hypoglycemic agents. The Committee recommended that immediate release formulation of glyburide and glipizide be chosen as the preferred oral hypoglycemic drugs.

10. Proton Pump Inhibitor Class Review

The utilization of proton pump inhibitors was reviewed by the P&T Committee in May 2003. Marian Mc Donagh, Pharm.D. from the OSHU-EPC presented the drug class review. The Committee recommended that Protonix remains the preferred proton pump inhibitor.

11. Calcium Channel Blocker Class Review

The utilization of calcium channel blockers was reviewed by the P&T Committee in May 2003. Marian McDonagh, Pharm.D. from the OSHU-EPC presented the calcium channel blocker class review.. The Committee recommended that the calcium channel blockers be considered as 2 classes, the dihydropyridines and the non-dihydropyridines. In addition, the council recommended all generic formulations of diltiazem and verapamil remain preferred drugs for the non-dihydropyridines, and nifedipine SR and amlodipine remain preferred drugs for the dihydropyridines,

12. Angiotensin Converting Enzyme Inhibitor Class Review

The utilization of ACEI was reviewed by the P&T Committee in July 2003. Mark Helfand, MD, from the OSHU-EPC presented the evidence based review of the ACEI. The Committee recommended that the three generic ACE inhibitors be preferred agents, with ramipril available for patients meeting the HOPE criteria.

13. HMG Co A Inhibitor Class Review

The utilization of HMG CoA Inhibitors was reviewed by the DUEC in July 2003. Mark Helfand, MD, from the OSHU-EPC presented the evidence based review of the HMG CoA inhibitors. The council recommended lovastatin and atorvastatin be preferred drugs for patients with lesser and greater LDL lower needs. In

addition, pravastatin should be available for patients at risk for drug interactions with the preferred HMG CoA reductase inhibitors.

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ATTACHMENT 4: DRUG UTILIZATION REVIEW BOARD ACTIVITIES

The Board heard a presentation by Dr. Chris Varley from the Division of Child and Adolescent Psychiatry, Department of Psychiatry and Behavioral Sciences, University of Washington, regarding the safety of anti-depressants in children and adolescents. The Board also heard stakeholder input regarding the use of anti-depressants in children and adolescents, and reviewed data regarding the utilization of anti-depressants in foster children in the custody of the Department of Social and Health Services (DSHS).

Based on Dr. Varley's presentation and the ensuing discussion, the DUR Board recommended that MAA provide educational guidance to Medicaid providers regarding antidepressant treatment for youth with major depressive disorder, and that this guidance parallel the position of the FDA.

The Board heard from Dr. Asha Singh and Cheryl Strange, both from the Division of Developmental Disabilities, regarding DDD's need to respond to a class action suit filed by the Washington Protection and Advocacy System (WPAS) on behalf of clients with developmental disability and mental health disorders. The Board recommended that in order to improve prescribing of psychoactive drugs to DD clients (as required by the Settlement Agreement), that MAA and DDD design an educational intervention with the top prescribers of psychoactive and/or anti-epileptic drugs rather than require the use of a specific tool for monitoring adverse effects.

The Board heard a presentation by Dr. Jeff Thompson, Chief Medical Officer for Medical Assistance Administration, regarding evidence-based prescribing of Cox-2 inhibitors. Dr. Thompson also reviewed data on the utilization of Cox-2 inhibitors. The Board endorsed an informal set of recommendations regarding guidelines for Cox-2 inhibitor prescribing that might be implemented by MAA to encourage evidence-based and cost-effective prescribing of these agents.

The Board heard a presentation by Jay Weaver, Pharm D., MPH, from Affiliated Computer Services (ACS) regarding an evaluation of the Washington State Therapeutic Consultation Service (TCS) Program. This presentation was informational only, and did not require any action of the Board. The Board learned that:

- Pharmacy users were more likely to remain on therapy following initiation of the TCS program

- There was no significant difference in average medical utilization or expenditure changes between participants who experienced a TCS edit and those who did not.
- More people were on appropriate medications for studied disease states in the post-TCS period than in the pre-TCS period.
- The most vulnerable population identified (dual eligibles) did not show any adverse health consequences.

The Board also reviewed data regarding pharmacy claims that have been submitted since the implementation of TCS in February 2002. The data presented suggested that the TCS program did not impede access to needed medications.

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ATTACHMENT 5: GENERIC DRUG POLICIES

The Therapeutic Consultation Service (TCS) four brand limit program, which began February 2002, continued during this fiscal year. A complete drug profile review by an MAA designated clinical pharmacist is performed with the prescriber when a client requests a fifth brand name prescription in a calendar month. The pharmacist reviews the profile and recommends less costly generic or preferred alternatives for the prescriber to consider. In addition the pharmacist reviews the entire drug profile for therapeutic duplications and drug-drug interactions to discuss with the prescriber. The prescriber may choose to accept the recommendation or the prescriber may choose to not accept the recommendation, and the prescription will be authorized for the current fill or for the life of the prescription if justification is provided by the prescriber.

Brand name drugs with two or more generic equivalents require prior authorization from MAA in order for the pharmacy to be paid for the brand name cost. These drugs have a maximum allowable cost assigned to them. The prescriber must provide medical justification to MAA in order for authorization to be granted for these brand name drugs.

- Drug classes experiencing greatest increase in generic utilization: hypoglycemics, cephalosporins, and ACE inhibitors in non-dual eligible FFS clients
- Drug classes experiencing greatest increase in generic utilization: cephalosporins, anti-virals, potassium products, and ACE inhibitors in dual eligible FFS clients

DUEC recommendations regarding generic utilization:

12/17/2003

The DUR board reviewed and recommended lower cost generic products to be included as preferred in both the beta blocker and estrogen drug classes.

March 17, 2004

The DUR board reviewed and recommended lower cost generic products to be included as preferred in the oral hypoglycemic, urinary incontinence and skeletal muscle relaxant classes drug classes. The exceptions in these classes were higher cost generics (cost equal or more than brands) and drugs with safety/abuse concerns such as carisoprodol.

June 16, 2004

Cyclo-oxygenase (COX) II inhibitor utilization and risks were presented and discussed. It was recommended to proceed and require prior authorization for brand name non-selective and COX-II inhibitor type non-steroidal anti-inflammatory drugs (NSAIDs). Generic NSAIDs will be preferred and require expedited prior authorization (EPA) with

the same requirement as all NSAIDs to prevent patients with a history of gastrointestinal bleed or ulcer from using them.

Lower cost generics included in the recommendation of preferred drugs after a review of the calcium channel blocker, non-steroidal anti-inflammatory drugs (NSAIDs), angiotensin converting enzyme (ACE) inhibitors, and long-acting opioids.

September 15, 2004

The DUR board recommended to include lower cost generic drugs as preferred in the statin and estrogen classes.

Jay Weaver, Pharm D, MPH, from Affiliated Computer Services (ACS) gave a presentation on the TCS program. DUR board members were presented with shifts in generic utilization and on health outcomes, medical utilization and compliance since the TCS program was implemented.

The conclusion was that the TCS program did not impede access to needed medications for targeted disease states, that providers and clients are successfully navigating the TCS program to maintain quality medication therapy, there appears to be no cost-shifting from pharmacy claim being denied to ER visits, and clients were more compliant with drug therapy for targeted disease states.

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State of Washington, DSHS MAA

ATTACHMENT 6: PROGRAM EVALUATION/COST SAVINGS

1. An evaluation to determine cost savings of two systems of assigning Maximum Allowable Costs: A computer data pull was designed to compare pharmacy reimbursement costs by applying the formula for the automated maximum allowable costs (AMAC) to the drugs for which a state maximum allowable cost (SMAC) had been assigned.

Findings: There was a savings of \$49,885,960 during FFY 2004 from the SMAC program. (See attachment)

2. An evaluation to estimate cost savings in the prospective DUR program that utilizes POS alerts: Data for Federal Fiscal Year 2002 were pulled to show savings from POS denied claims.

Findings: The POS DUR Summary Report shows that despite the fact that pharmacists overrode the conflict codes 53.3% of the time, 37.5% of the claims were denied as inappropriate, for a savings of \$23,036,781. (See attachment 2-2)

3. An evaluation to determine the rate of growth in the drug program expenditures compared drug costs as a percentage of total Medicaid health care costs for the last six years.

Findings:

<u>State Fiscal Year</u>	<u>% of total health care dollars</u>	<u>\$ spent on drugs</u>
1999	13.3%	\$239,748,244
2000	13.0%	\$305,168,298
2001	14.2%	\$366,098,336
2002	13.7%	\$421,344,000
2003	14.1%	\$442,472,637
2004	14.5%	\$492,035,175

4. An estimate of the cost savings attributed to the implementation of the Four Brand Cap and the Preferred Drug List (Therapeutic Consultation Service and Washington PDL). By September 2004, thirteen drug classes had been implemented.

2004 Findings:

Four Brand Cap savings	(budget estimate)	\$30,000,000
Preferred Drug List	(budget estimate)	\$19,460,532
Supplemental Rebate savings (10/1/03- 9/30/04):		\$ 2,302,810

5. Intensified Benefits Management (IBM):

Please see attachment 6-2 for a list of monthly IBM target interventions that were conducted during Federal Fiscal Year 2004 (October 2003 through September 2004).

The attachment shows the following for each month's targeted review:

- Drug class/educational intervention
- Number of clients targeted
- Number of Prescribers targeted
- Response rate
- Acceptance rate
- Estimated monthly or 3 month savings
- Estimated annual or 6 month savings

The January 2004 through April 2004 targeted reviews were informational only for prescriber education and no savings was estimated. Response rate and acceptance rate are not reported for these targeted reviews because no response or action was requested.

The savings from the IBM program are based on the targeted clients' prescribers' reaction to the faxes sent to them in the monthly review and their subsequent prescription activity compared to the pre-intervention prescription activity. While only a small number of clients (about 1000 per month) are actually involved in these targeted reviews, the impact on their prescribers carries across all the Medicaid clients they see. While IBM savings estimates are considered "soft" and are not additive to the savings from the Four Brand Cap or the Preferred Drug List, the IBM targeted reviews significantly contribute to the success and total savings estimated for these programs.